DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

93364d

August 9, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Eddie Schaap, Owner
North Point Dairy
2079 State Road #209
Clovis, New Mexico 88101

Ref. # : DEN-00-32

Dear Mr. Schaap:

Consumer Safety Officer Betty Kay Baxter conducted an investigation at your dairy operation located in Clovis, New Mexico, on May 16, 2000. The inspection confirmed that you offered an animal for sale for slaughter as food, in violation of sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On March 20, 2000 you sold a dairy cow, identified as USDA case #00-0471-NM, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from this animal identified the presence of penicillin residue of 0.78 parts per million (ppm) in the kidney. A tolerance of 0.05 ppm has been established for residues of penicillin in the edible tissues of cows in Title 21 Code of Federal Regulations Part 556.510 (21 CFR 556.510) at the time the analysis was conducted.

Our investigation revealed the use of Procaine Penicillin G. The presence of penicillin at the level found in the edible tissue from this animal causes the food to be adulterated within the meaning of section 402(a)(2)(C)(ii) of the Act.

Our investigation also found that you hold animals under inadequate conditions that may result in diseased and/or medicated animals bearing potentially harmful drug residues entering the food supply. For example, your animal treatment records do not indicate the dosage or route of drugs given. You lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions are adulterated within the meaning of section 402(a)(4) of the Act.

PURGED

You should notify this office in writing within 15 working days of the steps you have taken to bring your operation into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 30 working days, state the reason for the delay and the timeframe within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be sent to Regina A. Barrell, Compliance Officer, Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087. She may be reached at (303) 236-3043 if you have any questions about this matter.

Sincerely,

Thomas A. Allison
District Director

cc: Dr. Ronald K. Jones, D.V.M.
Boulder District Manager
USDA/FSIS
665 S. Broadway, Suite B
Boulder, CO 80303

[XXX]

[XXX]

PURGED